

# BioSystems

human centred biotech

Registered Office  
BioSystems Diagnostics Pvt. Ltd.,  
A4 SIPCOT Industrial Park, Irungattukottai,  
Tamil Nadu - 602106, India  
Ph: +91 44 30341911 / 12713116  
Email: support@biosystems.in  
CIN: U29297TN12003PTC0051492

## *BTS - Semi Auto Biochemistry Analyzer*

### *Operational Qualification For*

### *Enga Doctor Medical Diagnostic Center*

*BioSystems Diagnostics Pvt. Ltd.,*

BioSystems S.A  
Costa Brava 30,  
08030 Barcelona (Spain)  
T: +34 933 110 000

[www.biosystems.in](http://www.biosystems.in)  
[www.biosystems.global](http://www.biosystems.global)

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**BioSystems Diagnostics Pvt. Ltd.,**  
A4, SIPCOT Industrial Park, Irungattukottai,  
Tamil Nadu - 602105 India  
Ph: +91 44 30341911 / 12/ 13/14  
Email: support@biosystems.in  
CIN - U29207TN2603PTC051492

## *BTS– Semi Auto Biochemistry Analyzer*

### OPERATIONAL QUALIFICATION

1. System Decontamination
2. Maintenance Procedures
3. System Performance check procedures
4. Customer Training Operation and Maintenance

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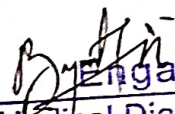
## CERTIFICATE OF OPERATION

Instrument Name : BTS - Semi Auto Biochemistry Analyser  
Serial Number : 0000001860  
Customer : Enga Doctor Medical Diagnostic Center

The undersigned performer certifies that the Operational Qualification Protocol has been successfully completed for the instrument stated above.

Authorized Signature : **S SENTHIL**  
Digitally signed by S SENTHIL  
DN: cn=S SENTHIL, c=IN,  
o=PERSONAL,  
email=S SENTHIL@BSYSTEMS.IN  
Date: 2014.04.25 15:22:10 +05'30'

Name : Mr. RAJENDRA KAMILAS  
Designation : Service Engineer  
Company : BioSystems Diagnostics Pvt. Ltd.,

Customer Signature :   
**Enga Doctor**  
**Medical Diagnostic Centre**  
**Palayamkottai, Tirunelveli**

Name : Ms. Bagavathy  
Designation : Lab Incharge  
Company : Enga Doctor Medical Diagnostic Center

## SYSTEM PERFORMANCE CHECK PROCEDURE

SYSTEM CHECK	PERFORMANCE
System Decontamination	Done
Photometer LED Check	Done
Start Up	Done
Pump Adjustments	Done
Temperature Check	Done

Customer Signature:

  
Sanga Doctor  
Medical Diagnostic Centre  
Palayamkottai, Tirunelveli

## OPERATIONAL QUALIFICATION

### System Certification:

Study data has determined that the System described in this document either meets all criteria outlined in this Operational Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any have been addressed. The system is ready for specified usage.

Protocol Performed By:

BioSystems Engineer

Name : Mr. RAJENDRA KAMILAS

Title : Service Engineer

Company: BioSystems Diagnostics Pvt. Ltd

Customer Authorization

Enga Doctor Medical Diagnostic Center

Name : Ms. Bagavathy

Title : Lab Incharge

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SENTHIL

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DN: cn=S SENTHIL, o=IN  
PERSONAL, email=S SENTHIL@BIOSYSTEMS.IN  
Date: 2024.06.25 15:43:27 +05'30'

AUTHORIZED SIGNATURE

DATE: 14.06.2024

EngaDoctor  
Medical Diagnostic Centre  
Palayamkottai, Tirunelveli

CUSTOMER SIGNATURE

DATE: 14.06.2024

**BioSystems**

INSTRUMENTS • LABORATORY EQUIPMENT

Registration Office

BioSystems (Hongkong) Pvt. Ltd.,  
2/F, 28th Floor, Industrial Park, Kowloon, Hong Kong  
Tel: (852) 2425 2246, 2425 2247  
Fax: (852) 2425 2247, 2425 2248  
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***BTS - Semi Auto Biochemistry  
Analyzer***

***Installation Qualification Certificate***

***For***

***Enga Doctor Medical Diagnostic  
Center***

***BioSystems Diagnostics Pvt. Ltd***

BioSystems S.A.  
C/Gran Via 30  
08020 Barcelona (Spain)  
Tel: +34 933 132 000

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[www.biosystems.global](http://www.biosystems.global)

## INSTALLATION REPORT

Customer Name : **Enga Doctor Medical Diagnostic Center**

Department : **Bio Chemistry Analyzer**

Contact Person : **Ms. Bagavathy**

Instrument Model : **BTS Semi Auto Analyzer**

Serial Number : **0000001860**

Date of Installation : **14-09-2021**

The System was installed along with the necessary accessories. All basic requirements and adjustments were checked and are found to be satisfactory. Preliminary customer training was provided and standardization of a few parameters was done. The Instrument is found to be working satisfactorily.

## CERTIFICATE OF INSTALLATION

Instrument Name: BTS - Semi Auto Biochemistry Analyzer

Serial Number : 0000001860

Customer : **Enga Doctor Medical Diagnostic Center**

The undersigned performer certifies that the installation Qualification Protocol has been successfully completed for the instrument stated above.

Authorized  
Signature :

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o=PERSONAL,  
email=SENTHIL@BIOSYSTEMS.IN  
Date: 2024.06.25 15:32:11 +05'30'

Name : Mr. RAJENDRA KAMILAS

Designation : Service Engineer

Company : BioSystems Diagnostics Pvt. Ltd

Customer  
Signature :

  
**Enga Doctor**  
Medical Diagnostic Centre  
Palayamkottai, Tirunelveli

Name : Ms. Bagavathy

Designation : Lab Incharge

Company : **Enga Doctor Medical Diagnostic Center**



## INSTALLATION QUALIFICATION

Customer Name : Enga Doctor Medical Diagnostic Center

Address : # 10j,1, Triuvandram road, Palayamkottai,  
Tirunelveli - 627002

Instrument Model : BTS

Serial No. : 0000001860

### *Operational requirement for the Instrument:*

Requirement	Acceptable Range	Observed Range
Input Voltage	220 $\pm$ 10 V	222 V
Line Frequency	50 or 60 Hz	51 Hz
Ambient Temperature	18 – 30 deg. C	22 deg. C

For Biosystems Diagnostics Pvt. Ltd.,

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email=SENTHIL@BIOSYSTEMS.IN  
Date: 2024.06.25 15:32:52 +05'30'

Mr. RAJENDRA KAMILAS  
Service Engineer

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## *BTS - Semi Auto Biochemistry Analyzer*

### *Performance Qualification*

#### *For*

### *Enga Doctor Medical Diagnostic Center*

## *BioSystems Diagnostics Pvt. Ltd*

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## **BTS - SEMIAUTO BIOCHEMISTRY ANALYSER**

### PERFORMANCE QUALIFICATION:

- Pump Adjustment done and performance also checked
- Few test parameters, controls run and checked the results and found results are coming within the range

LED	INTENSITY	INTEGRATION TIME (ms)
340	100	05
405	201	30
505	205	10
535	95	07
560	100	16
600	201	36
635	197	09
670	94	14

## CERTIFICATE OF PERFORMANCE

Instrument Name : BTS - Semi Auto Biochemistry Analyser  
Serial Number : 0000001860  
Customer : **Enga Doctor Medical Diagnostic Center**

The undersigned performer certifies that the Performance Qualification Protocol has been successfully completed for the instrument stated above.

Authorized  
Signature

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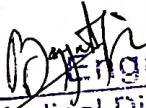
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o=PERSONAL,  
email=SENTHIL@BIOSYSTEMS.IN  
Date: 2024.06.25 15:33:42 +05'30'

Name : Mr. RAJENDRA KAMILAS

Designation : Service Manager

Company : BioSystems Diagnostics Pvt. Ltd

Customer  
Signature

:   
**Enga Doctor**  
**Medical Diagnostic Centre**  
Palavankottai, Tirunelveli

Name : Ms. Bagavathy

Designation : Lab Incharge

Company : **Enga Doctor Medical Diagnostic Center**

